

REMARKS

The Examiner reiterates that priority is given for the instant filing date of March 31, 1998 since no clarification or explanation was given by Applicant. Applicant respectfully requests the Examiner's permission to submit the comparison of sequences disclosed in the parent application with those claimed in the instant invention.

Claims 10-16, 25, 30, 35 and 38-43 remain rejected under 35 USC 101 because the specification does not disclose any diseases or conditions known to be associated with the claimed polynucleotide sequences. These claims have been cancelled.

Applicant respectfully disagrees. The specification teaches that the claimed sequences express themselves more abundantly in prostate tissue than any other tissue, thereby establishing that prostate tissue is the host tissue of the claimed gene products.

Several assays utilizing the overexpression of tissue-specific gene products have been established in the art. The court has consistently stated that claim language must be read in light of prior art and teachings of the specification. The standard is that the "definiteness of the language must be analyzed...in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

Applicant has previously described how gene products that are expressed in a host tissue but not in other tissue can be used to indicate disease when they are found to be overexpressed in tissue outside their host tissue (e.g., CEA, PSA). Such overexpression indicates that a disease has altered the polynucleotides so that they escape from their host tissue (in this case prostate tissue) into other areas of the body, such as blood. These examples demonstrate that presence of the claimed gene products outside normal host tissue serves as a diagnostic indicator that the host tissue is in a diseased state. Thus, the

correlation to disease states of tissue-specific gene products such as those claimed in the present invention are established in the art. Because the claims should be analyzed in light of the teachings of the prior art and well-known techniques of immunohistochemistry for assessing overexpression are incorporated into the specification, Applicant asserts that the examples and methods disclosed in the specification are enabled for detecting, at the least, prostate diseases that may be detected using gene markers and related gene marker technology. Applicant respectfully submits that new claims 44-58 are now in a condition for allowance and requests that this rejection be withdrawn.

Claims 10-16, 25, 30, 35 and 38-43 remain rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. These claims have been canceled. Moreover, Applicant asserts that in light of the above amendments and remarks, the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 10-16, 25, 30, 35 and 38-43 remain rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventor had possession of the claimed invention at the time the application was filed. These claims have been canceled.

The Examiner has stated that "with the exception of SEQ ID NOS:1-9, 12, 13 or polynucleotides encoding SEQ ID NOS:24-28 and degenerative coding sequences thereof", the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides. Applicant respectfully disagrees. Several methods are established in the art and cited in the specification for envisioning the detailed structure within the context of percent identity variants. However, in an effort to expedite prosecution, new claims 44-58 do not contain "percent identity" language. Furthermore, new claims 44-58 encompass degenerate coding sequences thereof. The degeneracy of the genetic code is a concept that is well known to those skilled in the art and is even discussed in section 2144.09 of the February 2000 revision of the Manual for Patent Examining Procedure as "the fact that most amino acids are specified by more than one nucleotide sequence or codon." Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

The Examiner further states that the specification does not enable any person skilled in the art to make and use the invention commensurate in scope with the claims. The Examiner states that "the specification would still be enabling only for claims limited to the polynucleotides of SEQ ID NOS:1-9, 12 or 13 and polynucleotides encoding SEQ ID NOS:24-28 and degenerate coding sequences thereof, and the complete complement of said and a method of producing a polypeptide comprising SEQ ID NOS:24-28".

Applicant respectfully disagrees. As stated above, several methods are established in the art and cited in the specification for envisioning the detailed structure within the context of percent identity variants. However, in an effort to expedite prosecution, new claims 44-58 do not contain "percent identity" language. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

CONCLUSION

In view of the aforementioned amendments and remarks, Applicant respectfully submits that the above-referenced application is now in a condition for allowance and Applicant respectfully requests that the Examiner withdraws all outstanding objections and rejections and passes the application to allowance.

Respectfully submitted,
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